

WHAT IS CLAIMED IS:

1 1. A process for preparing a pharmaceutical composition comprising as
2 an active ingredient a hygroscopic salt of valproic acid, comprising the step of intimately
3 mixing (i) said hygroscopic salt; (ii) a carbomer and (iii) a non-hygroscopic additive to
4 form a homogeneous mixture; wherein the amount of said carbomer and said non-
5 hygroscopic additive are sufficient relative to the amount of said hygroscopic salt to
6 produce said mixture having the following property: when compressed into tablets, said
7 tablets do not absorb more than 5% water by weight after being stored for 3 months at
8 75% relative humidity.

1 2. The process of claim 1, wherein said hygroscopic salt of valproic acid
2 is sodium valproate.

1 3. The process of claim 1, wherein the weight ratio of carbomer to the
2 hygroscopic salt of valproic acid ranges from about 1:3 to about 1:100.

1 4. The process of claim 1, wherein the weight ratio of carbomer to the
2 hygroscopic salt of valproic acid ranges from about 1:3 to about 1:10.

1 5. The process of claim 1, wherein the weight ratio of non-hygroscopic
2 additive to the hygroscopic salt of valproic acid ranges from about 1:6 to about 1:2.

1 6. The process of claim 1, further comprising a step of adding at least
2 one excipient to the mixture of said hygroscopic salt, said carbomer and said non-
3 hygroscopic additive.

1 7. The process of claim 1, further comprising a step of compressing said
2 non-hygroscopic composition into a solid dosage form.

1 8. The process of claim 7, wherein said solid dosage form contains from
2 about 50 to about 1200 mg of sodium valproate.

1 9. The process of claim 8, wherein said solid dosage form contains from
2 about 6 mg to about 400 mg of carbomer.

1 10. The process of claim 9, wherein, said solid dosage form contains from
2 about 90 mg to about 400 mg of non-hygroscopic additive.

1 11. The process of claim 3, wherein said non-hygroscopic additive is
2 selected from the group consisting of dibasic calcium phosphate anhydrous, calcium
3 silicate, microcrystalline cellulose and mixtures thereof.

1 12. The process of claim 3, wherein said non-hygroscopic additive is
2 present in an amount such that the weight ratio of non-hygroscopic additive to the
3 hygroscopic salt of valproic acid is in the range of from about 1:6 to 1:2.

1 13. The process of claim 6, wherein said excipient is selected from the
2 group consisting of lubricants, disintegrators, glidants, adsorbents, and mixtures thereof.

1 14. The process of claim 13, wherein said lubricant is selected from the
2 group consisting of stearic acid, a salt of stearic acid, talc, sodium lauryl sulfate, sodium
3 stearyl fumarate and mixtures thereof.

1 16. The process of claim 13, wherein said disintegrator is selected from
2 the group consisting of crosscarmellose sodium, sodium starch glycolate, starch,
3 magnesium aluminum silicate, colloidal silicon dioxide, carboxymethyl cellulose,
4 microcrystalline cellulose, and mixtures thereof.

1 17. The process of claim 16, wherein said disintegrator is present in an
2 amount of from about 0.5% to about 25% of the weight of the final composition.

1 18. The process of claim 12, wherein said glidant is selected from the
2 group consisting of colloidal silicon dioxide, talc and mixtures thereof.

1 19. The process of claim 18, wherein said glidant is present in an amount
2 of from about 0.1 % to about 10% of the weight of the final composition.

1 20. The process of claim 13, wherein said adsorbent is selected from the
2 group consisting of colloidal silicon dioxide, microcrystalline cellulose, calcium silicate
3 and mixtures thereof.

21. The process of claim 20, wherein said adsorbent is present in an amount of from about 0.05% to about 42% of the weight of the final composition.

1 22. The process of claim 7, wherein said solid dosage form is selected
2 from the group consisting of a tablet, a caplet, a pellet, a capsule, a tablet which
3 disintegrates into granules, and a pill.

1 29. The pharmaceutical composition of claim 27, wherein the weight
2 ratio of carbomer to the hygroscopic salt of valproic acid ranges from about 1:3 to about
3 1:100.

1 30. The pharmaceutical composition of claim 27, wherein the weight ratio
2 of carbomer to the hygroscopic salt of valproic acid ranges from about 1:3 to about 1:10.

1 31. The pharmaceutical composition of claim 29, wherein the non-
2 hygroscopic additive is present in an amount such that the weight ratio of non-
3 hygroscopic additive to the hygroscopic salt of valproic acid is in the range of from about
4 1:6 to about 1:2.

1 32. The pharmaceutical composition of claim 31, wherein said non-
2 hygroscopic additive is present in an amount such that the weight ratio of the non-
3 hygroscopic additive to the carbomer is in the range of from about 2:1 to about 35:1.

1 33. The pharmaceutical composition of claim 27, further comprising at
2 least one excipient.

1 34. The pharmaceutical composition of claim 27, wherein the
2 composition contains from about 50 to about 1200 mg of sodium valproate.

1 35. The pharmaceutical composition of claim 34, wherein the
2 composition contains from about 6 mg to about 400 mg of carbomer.

1 36. The pharmaceutical composition of claim 35, wherein the
2 composition contains from about 90 mg to about 400 mg of non-hygroscopic additive.

1 37. The pharmaceutical composition of claim 27, wherein said
2 non-hygroscopic additive is selected from the group consisting of dibasic calcium
3 phosphate anhydrous, calcium silicate, microcrystalline cellulose and mixtures thereof.

1 38. The pharmaceutical composition of claim 27, further comprising an
2 excipient selected from the group consisting of lubricants, disintegrators, glidants,
3 adsorbents, and mixtures thereof.

1 39. The pharmaceutical composition of claim 38 wherein said lubricant is
2 selected from the group consisting of stearic acid, a salt of stearic acid, talc, sodium
3 lauryl sulfate, sodium stearyl fumarate and mixtures thereof.

1 40. The pharmaceutical composition of claim 39, wherein said lubricant
2 is present in an amount of from out 0.25% to about 5% of the weight of the final
3 composition.

1 41. The pharmaceutical composition of claim 38 , wherein said
2 disintegrator is selected from the group consisting of crosscarmelose sodium, sodium
3 starch glycolate, starch, magnesium aluminum silicate, colloidal silicon dioxide,
4 carboxymethyl cellulose, microcrystalline cellulose, and mixtures thereof.

1 42. The pharmaceutical composition of claim 41, wherein said
2 disintegrator is present in an amount of from about 0.5% to about 25% of the weight of
3 the final composition.

1 43. The pharmaceutical composition of claim 38, wherein said glidant is
2 selected from the group consisting of colloidal silicon dioxide, talc and mixtures thereof.

1 44. The pharmaceutical composition of claim 43, wherein said glidant is
2 present in an amount of from about 0.1 % to about 10% of the weight of the final
3 composition.

1 45. The pharmaceutical composition of claim 38, wherein said adsorbent
2 is selected from the group consisting of colloidal silicon dioxide, microcrystalline
3 cellulose, calcium silicate and mixtures thereof.

1 46. The pharmaceutical composition of claim 45, wherein said adsorbent
2 is present in an amount of from about 0.05% to about 42% of the weight of the final
3 composition.

1 47. The pharmaceutical composition of claim 27, wherein the
2 non-hygroscopic oral pharmaceutical composition is a tablet, a caplet, a pellet, a capsule,
3 a tablet which disintegrates into granules, and a pill.

1 48. The pharmaceutical composition of claim 47, wherein the tablet is an
2 enteric coated tablet.

1 49. The pharmaceutical composition of claim 48, wherein the tablet is
2 coated with an anti-moisture barrier.

1 50. The pharmaceutical composition of claim 27, wherein the
2 non-hygroscopic oral pharmaceutical composition is a sustained release tablet wherein
3 the weight ratio of carbomer to the hygroscopic salt of valproic acid ranges from about
4 1:6 to about 1:20.

1 51. The pharmaceutical composition of claim 50, wherein the
2 non-hygroscopic oral pharmaceutical composition is a sustained release tablet.

1 52. A method of treating a medical condition in a human patient, the
2 method comprising the step of orally administering a non-hygroscopic pharmaceutical
3 composition for release of a salt of valproic acid into the bloodstream at a physiologically
4 effective level, wherein said composition comprises a pharmaceutically effective amount
5 of a hygroscopic salt of valproic acid, a carrier, and a non-hygroscopic additive, and
6 wherein the weight ratio of the carbomer to the hygroscopic salt of valproic acid is from
7 about 1:3 to about 1:100 and the weight ratio of the non-hygroscopic additive to the
8 hygroscopic salt of valproic acid is from about 1:6 to about 1:2 .

1 53. The method of claim 52, wherein said medical condition is epilepsy.

1 54. The method of claim 52, wherein said medical condition is a
2 psychotic disorder.

1 55. The method of claim 52, wherein said medical condition is a
2 migraine headache.